

**UNITED STATES DISTRICT COURT
FOR THE NORTHER DISTRICT OF OHIO
EASTERN DIVISION**

**IN RE NATIONAL PRESCRIPTION
OPIATE LITIGATION**

This document relates to:

Track Three Cases

MDL No. 2804

Case No. 17-md-2804

Judge Dan Aaron Polster

**REPLY MEMORANDUM IN FURTHER SUPPORT OF
CERTAIN DEFENDANTS' *DAUBERT* MOTION
TO EXCLUDE THE OPINIONS OFFERED BY JAMES RAFALSKI**

Certain Defendants¹ moved to exclude Rafalski's opinions in CT3 on three grounds:

(1) his CT3 Report blatantly disregarded this Court's CT1 Order on the permissible limits of his opinions; (2) his opinions as to Moving Defendants' SOM systems were not actually based on his professional experience as a DEA Diversion Investigator, but instead used unreliable methods custom-made for this litigation; and (3) his cursory causation opinions did not use reliable methods to analyze whether Moving Defendants' opioids were substantially involved in the opioids crisis in Lake and Trumbull Counties. Plaintiffs in Opposition failed to meet their burden on any of these issues, or to otherwise show how Rafalski's opinions as to Moving Defendants could be admissible under binding Sixth Circuit case law. The Court therefore should exclude Rafalski's opinions as to Moving Defendants.

¹ Rite Aid Hdqtrs. Corp., Rite Aid of Ohio, Inc., Rite Aid of Maryland, Inc., d/b/a Rite Aid Mid-Atlantic Customer Support Center and Eckerd Corp. d/b/a Rite Aid Liverpool Distribution Center have been severed from this action. Moving Defendants are now Walmart Inc. and Giant Eagle, Inc. and HBC Service Company.

I. ARGUMENT

A. Rafalski blatantly disregarded the Court's prior Order

The Court could not have been clearer in CT1: “[T]o the extent Rafalski expresses opinions as to what the law requires, or whether the Defendants’ conduct violated the law, his opinions are not admissible.” Doc. 2494 (the “CT1 Order”) at *8. Rafalski’s CT3 Report repeatedly and blatantly violated this holding, and the Court should reaffirm its CT1 holding by excluding all such opinions.

CT3 Plaintiffs do not seek reconsideration of the Court’s CT1 Order, but instead inexplicably argue that Rafalski has not violated it. Opp. at 9. A few brief examples suffice to show otherwise.

Rafalski explicitly reported, “I am prepared to testify regarding the regulatory duties imposed by the CSA and federal regulations.” Rep. at 7 (attached as Exhibit 1). He further explicitly reported, “I have been asked to review the documents produced by the defendants and depositions taken in MDL2804 . . . and offer opinions regarding statutory and regulatory compliance.” *Id.* Rafalski then opined that:

The Controlled Substance Act (CSA) is designed to provide for a closed delivery system related to the pharmaceutical supply chain. The CSA requires DEA registration for each member of the closed supply chain, known as a registrant. . . . As a member of the closed delivery system each registrant takes on certain statutory and regulatory obligations to ensure the safety and efficiency of the pharmaceutical supply chain. . . . Under the CSA and the implementing regulations the distributors have two significant obligations that are designed to ensure that these controlled substances do not veer outside of the closed supply chain. These statutory and regulatory obligations come from:

- o 21 U.S.C.A. § 823(b)(1); which requires the “maintenance of effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels.”

- o 21 C.F.R. § 1301.74(b); which require the registrant to “design and operate a system to disclose to the registrant suspicious orders

of controlled substances.” Then the registrant is required to notify the DEA of all identified suspicious orders prior to shipment.

Rep. at 8. These reported opinions have the same form and substance as proposed jury instructions, they are statements of the law within the Court’s domain, and they are clearly inadmissible as expert opinions under the CT1 Order.

Rafalski then began a section he explicitly titled “Statutory Duty”:

Each distributor/pharmacy owes a duty to maintain effective control against diversion of prescription opiates into the illicit market. 21 U.S.C.A. § 823(b)(1) [1970].

The Controlled Substances Act (“CSA”) and its implementing regulations create restrictions on the distribution of controlled substances. *See* 21 U.S.C. §§ 801–971 (2006); 21 C.F.R. §§ 1300–1321 (2009). The main objectives of the CSA are to conquer drug abuse and to control the legitimate and illegitimate traffic in controlled substances. Congress was particularly concerned with the need to prevent the diversion of drugs from legitimate to illicit channels. To effectuate these goals, Congress devised a closed regulatory system making it unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the CSA. The CSA categorizes all controlled substances into five schedules. The drugs are grouped together based on their accepted medical uses, the potential for abuse, and their psychological and physical effects on the body. Each schedule is associated with a distinct set of controls regarding the manufacture, distribution, and use of the substances listed therein. . . .

Id. at 9. This passage reads like a legal brief that merely expresses the opinions of a non-lawyer as to what the law requires. It is not an admissible expert opinion. The Court already has made clear that such opinions are not admissible.

Rafalski then concluded this “Statutory Duty” section with his ultimate opinion that:

Based on my review of all the relevant documents and testimony taken in this case (MDL 2804) it is my opinion to a reasonable degree of professional certainty that the multiple distributors servicing Lake County and Trumbull County failed to maintain effective control against diversion of prescription opiates into other than legitimate medical, scientific, and industrial channels in violation of 21 U.S.C.A. § 823(b)(1).”

Id. at 10-11 (emphasis added). Again, this is an expression of Rafalski's opinion as to "whether the Defendants' conduct violated the law," and therefore his CT3 Report is in direct violation of the Court's CT1 Order.

The next section of Rafalski's CT3 Report, explicitly titled "Regulatory Duty," likewise is simply Rafalski's legal brief on what he believes that the DEA's security regulations require. Rep. at 11. Rafalski continued on with this sort of legal discussion, reviewing various legal authorities, including cases, DEA administrative actions, DEA guidance letters, DEA manuals, Healthcare Distribution Alliance policies, and so on, through Page 40 of his Report. *See* Rep. at 2 (Table of Contents). Adding to his pronouncements on the law, Rafalski's section titled "Maintenance Of Effective Controls Against Diversion Of Controlled Substances," included his opinion on which measures registrants "must implement . . . to comply with legal and regulatory standards." Rep. at 40. Again, these are all inadmissible expressions of Rafalski's opinions on what the applicable law and regulations require. For his finale, Rafalski conceded that he described in "[his] report . . . the defendants' inadequate response to their statutory and regulatory requirements" Rep. at 45. Again, Rafalski reported an opinion that Moving Defendant's conduct violated their statutory and regulatory requirements, as previously briefed by Rafalski, all in blatant disregard of the Court's CT1 Order.

The Court's unchallenged CT1 holding is that it is solely the Court's job to determine Moving Defendants' statutory and regulatory requirements, while the jury must determine whether or not Moving Defendants' conduct violated those requirements. Rafalski overstepped those boundaries in his CT3 Report and the Court should again hold that all such opinions are inadmissible.

B. Because Rafalski does not use the methods he used professionally, his testimony is unreliable.

The admissibility of the opinions of an expert with a professional background depends on whether the expert actually uses the methods he previously used professionally. *See Johnson v. Manitowoc Boom Trucks, Inc.*, 484 F.3d 426, 434-35 (6th Cir. 2007). In cases where the expert does use his prior methods, it may be appropriate for the trial judge to apply the *Daubert* factors in a “somewhat more lenient fashion.” *Id.* at 435. But where, as here, the expert uses new methods created specifically for the litigation, “the party proffering the expert must show some objective proof . . . supporting the reliability of the expert’s testimony.” *Id.* (emphasis added).

The Sixth Circuit’s *Johnson* rule is easy to apply: if Plaintiffs are going to qualify an expert based on his professional experience and then ask a factfinder to rely on his opinions as evidence, his opinions must actually make use of his professional experience. If that expert instead adopts new methods for the purposes of litigation, Plaintiffs must go further and provide objective proof of the reliability of these new methods; merely citing the expert’s professional experience is no longer sufficient to meet their burden on admissibility. Plaintiffs have not, and cannot, make such a showing as to Rafalski’s made-for-litigation methods for analyzing Moving Defendants’ SOM systems.

Unable to make this showing, Plaintiffs argue Rafalski was not required to follow “the exact steps he would have taken as a DEA Diversion Investigator,” that he asserts that he was drawing on his experience as a DEA Diversion Investigator when following Plaintiffs’ new preferred method of merely reviewing selected documents and depositions (which conveniently always results in a pro-plaintiff opinion against every defendant), and therefore that the Court should follow the more lenient prong of the *Johnson* standard. *See Opp.* at 10-11. But as Moving Defendants already detailed, Rafalski’s methods were counsel-driven, developed

specifically for this litigation, and do not even remotely resemble the reliable methods he was trained to use as a DEA Diversion Investigator.

For example, Plaintiffs have no answer as to why Rafalski failed to physically inspect Moving Defendants' facilities, as he had a right to do under the Federal Rules, and as Moving Defendants' own expert did. Plaintiffs' counsel simply assert on his behalf that he did not have to, but Rafalski himself admitted in his deposition that doing so was "important." Tr. 454-55, 461-62. Apparently, Plaintiffs' counsel never informed Rafalski that it was an option. Tr. 440. Plaintiffs' counsel cannot keep Rafalski in the dark about the means of investigation available to him, and then assert that Rafalski did not need them—especially when Rafalski himself testified those methods were important.

Plaintiffs also try to redeem Rafalski's failure to review Moving Defendants' inspection reports by arguing that even if he had reviewed the reports, there might have been some reported shortcomings. Opp. at 13. But Plaintiffs' counsel are not the experts, and they are not permitted to do the required expert work for Rafalski and speculate about what he would have concluded if he had actually reviewed those reports. Reviewing prior inspection reports was a required first step for all DEA Diversion Investigators and, as such, Plaintiffs cannot absolve Rafalski of his responsibility to follow those methods while at the same time arguing he is entitled to a lenient admissibility standard as an expert purportedly relying on his professional experience.²

² Plaintiffs also quote Rafalski as testifying he would not place "a high value" on reviewing prior inspections. Opp. at 13. Rafalski did not testify he would place no value on reviewing prior inspections, and in fact in the same answer he also stated, "I wouldn't say it wasn't important." Tr. at 455. It defies basic plausibility that a neutral expert would not at least review and discuss Moving Defendants' DEA and BOP inspection reports when analyzing their compliance with the applicable regulations. And in fact, when confronted in his deposition with material from Moving Defendants' reports that appeared to contradict his opinions, he explicitly stated, "I would like to read the report." Tr. at 459. Rafalski therefore acknowledged the importance of such a review, he simply did not do it when preparing his opinions as to Moving Defendants.

In a mere footnote, Plaintiffs try to defend Rafalski's complete failure to include Moving Defendants' pharmacies within the scope of his investigation on the same ground that Rafalski offered in his testimony: that Plaintiffs never asked Rafalski to do so. *See* Opp. at 14 n.2. Again, that is no excuse for Rafalski failing to perform the sort of investigation of Moving Defendants' pharmacies that he admitted he would have performed as a DEA Diversion Investigator. Instead, it merely underscores that it was Plaintiffs' counsel, and not their hired expert, who determined what methods Rafalski would use—and what methods he would ignore—to further Plaintiffs' interests in this litigation.

In fact, Rafalski testified that as a DEA Diversion Inspector, he specifically relied on objective pharmacy-level metrics like cash payment percentages, total prescription dispensing volume, and the ratio of controls to non-controls. Tr. 123-24. Such metrics allow the DEA to more reliably identify which specific opioids are more or less likely to be diverted. But Rafalski's only excuse for not using these metrics when investigating Moving Defendants, who again only supplied opioids to Lake and Trumbull Counties through their own pharmacies, was that nobody asked him to consider these metrics in this case. Tr. at 124.³

These and other facts confirm that the Court must apply the second, more exacting, prong of *Johnson*. Rafalski's methods as applied to Moving Defendants were made for litigation, and indeed governed by instructions from Plaintiffs' counsel. Plaintiffs therefore had the burden of

³ Which is likely because as applied to Moving Defendants, those metrics would have given Plaintiffs answers that they did not want—namely, that given these metrics, it is highly unlikely that diversion from Moving Defendants' pharmacies was a significant source of opioids in the illicit markets of Lake and Trumbull Counties. Although Plaintiffs rightly argue that an expert's testimony is not inadmissible merely because of the conclusions the expert reaches, Plaintiffs cannot then use that principle as a loophole to instruct their hired expert to simply ignore evidence that he would ordinarily consider important, but that would be contradictory to Plaintiffs' desired conclusions. *Daubert* does not permit this kind of willful blindness by an expert.

providing objective proof of the reliability of those methods. Because they did not provide such proof, his opinions are inadmissible under Sixth Circuit case law.

Even if they had tried, Plaintiffs could not meet the *Johnson* burden because Rafalski's made-for-litigation methods are objectively *unreliable*. It is part of the DEA's core mission to devise reliable methods for detecting and investigating possible violations of their regulations regarding the security of scheduled drugs. The DEA accordingly trains its Diversion Investigators to do important things like physically inspect facilities, carefully review prior inspection reports, tailor their methods to the nature of the business entity involved (including investigating the pharmacies of self-distributors using standard metrics), and consider the entity's security measures holistically, precisely because there is no one approach to a SOM system that is required by DEA regulations for all types of entities. As the DEA itself recognizes, different entities can achieve substantial compliance with the DEA's security regulations in different ways. Thus, a reliable method for evaluating the compliance measures of any one entity must be carefully individualized to that entity.

Instead, at the direction of Plaintiffs' counsel, Rafalski devised a one-size-fits-all method that he applied to all of the defendants, stripping out any of the individualized methods that he would have used as a DEA Diversion Investigator. That is not a reliable approach; it is not based on Rafalski's professional experience; and it only has the "virtue" of always—with respect to every single defendant Rafalski has examined across all the related cases—giving Plaintiffs the opinion that they paid to get. Such made-for-litigation testimony, without an objective showing of reliability, is not admissible in the Sixth Circuit.

C. Rafalski's causation opinions are inadmissible under binding Sixth Circuit precedent

An expert cannot provide a causation opinion as to a particular defendant unless the expert's analysis covers a complete causal chain from the known actions of the defendant to the alleged harm. *See Nelson v. Tenn. Gas Pipeline Co.*, 243 F.3d 244, 253-54 (6th Cir. 2001). In *Nelson*, the defendants had introduced certain chemicals into the relevant environment, and the expert sought to provide the opinion that the defendants' chemicals had caused plaintiffs' relevant neurological and pulmonary abnormalities. *Id.* at 247, 252. The Sixth Circuit held that these opinions were properly excluded because the expert did not evaluate whether plaintiffs were actually exposed to defendants' chemicals, if so the degree of that exposure, or finally whether there were other confounding factors. *Id.* at 253-54.

Rafalski did exactly what the rejected expert in *Nelson* sought to do. He purported to have reviewed seven methodologies by which Moving Defendants could have flagged some orders from their pharmacies as possibly suspicious and worth further investigation. He did not opine that DEA regulations required Moving Defendants to use these methodologies, and instead admitted they could have used other monitoring methods that he did not evaluate. And as applied to Moving Defendants, the methods he did consider gave wildly varying results, including in some cases flagging no orders at all.

Rafalski then leapt from this starting point to the Plaintiffs' desired conclusion that Moving Defendants' opioids were "a substantial cause of the opioid epidemic plaguing the country and specifically in Lake County and Trumbull County." Rep. at 7. But Rafalski admitted doing nothing to assess whether Moving Defendants' opioids were actually diverted in these counties, or in what quantities, or what role was played by confounding factors. Like the expert in *Nelson*, his speculative causation opinions are not admissible.

Plaintiffs in part try to redeem Rafalski's causation opinions by abandoning his other six methodologies and stating he only intends to rely on the particular methodology used in *Masters*, Methodology A. Opp. at 16. But again, Plaintiffs' counsel cannot speak for the expert. And Rafalski himself never reported the opinion that only Methodology A is reliable. In fact he admitted in his deposition that a registrant did not have to use any of the seven methodologies, and that using a manual system instead could comply with the SOM regulations. Tr. 319, 326-27.

Rafalski's actual causal logic is that Moving Defendants failed to comply with the requirements of the Controlled Substances Act (itself an inadmissible legal conclusion), and that this failure then caused opiate pills to "flood[] the illicit market in CT3 jurisdictions." Rep. at 57. But as applied to Moving Defendants, neither his methodologies collectively, nor Methodology A alone (as Plaintiffs' counsel now urge), show that Moving Defendants actually failed to comply with the requirements of the Controlled Substances Act. So, Rafalski's proposed causal chain does not even get to the first step.

Rafalski also completely fails to justify leaping to the final step. Plaintiffs suggest that the Court should ignore the clear and binding holding of *Nelson* as applied to the admissibility of expert testimony. But they do not cite any Sixth Circuit published opinions on expert admissibility, instead notably relying on the Court's prior decision on a summary judgment issue. Opp. at 17-18.

In Doc. 2561 ("CT1 Causation Order"),⁴ the Court held that assuming the factfinder concluded the CT1 Defendants completely failed to maintain effective controls against diversion,

⁴ Moving Defendants preserve their objections to, and reserve the right to challenge, the CT1 Causation Order.

the factfinder could reasonably infer these failures were a substantial cause of the alleged harm suffered by Plaintiffs. *See* CT1 Causation Order at *9. Given the Rule 56 standard, the Court held that summary judgment against the CT1 plaintiffs on this issue was inappropriate. *Id.* (citing *BCS Servs., Inc. v. Heartwood 88, LLC*, 637 F.3d 750, 758 (7th Cir. 2011) (discussing what evidence a plaintiff must present to withstand summary judgment on causation)).

In light of that holding, Plaintiffs may make this sort of argument to the CT3 jury. But Rafalski is not the factfinder. Under cases like *Nelson*, Plaintiffs cannot have a purported expert make such an inference, with no actual reliable methodology to support that inference, and then present that testimony to the jury as reliable and admissible expert opinion evidence. Plaintiffs are intentionally conflating the ultimate conclusions that the factfinder can permissibly reach with the sorts of expert analysis that a party can offer as opinion evidence. And testifying on ultimate conclusions, rather than providing reliable expert analysis, is precisely what the Court already held that Rafalski cannot do. CT1 Order at *8.

Plaintiffs try to evade the Sixth Circuit's clear holding in *Nelson* by citing to the dissent in another Sixth Circuit case, *Tamraz v. Lincoln Elec. Co.*, 620 F.3d 665 (6th Cir. 2010). *See* Opp. at 4 (citing *Tamraz*, 620 F.3d at 682 (dissenting opinion)). And Plaintiffs are in fact making the same sort of plea for leniency as the losing party in *Tamraz*, an argument that the *Tamraz* court rejected.

Tamraz involved a welder who suffered symptoms of parkinsonism, and who sued manufacturers of welding supplies alleging manganese in their products caused his symptoms. 620 F.3d at 667. The Sixth Circuit held that the trial court erred in admitting the causation opinion of a medical doctor who testified that defendants' manganese products likely caused plaintiff's parkinsonism. *See id.* at 669-72. The *Tamraz* court observed that the expert's opinion

was a “plausible hypothesis.” *Id.* at 670. But because the expert did not then go on to reliably test that hypothesis, and instead engaged in several “speculative jumps” in the causal chain, including a failure to rule out alternative causes, the Sixth Circuit held the expert’s causation opinions were inadmissible under Rule 702. *Id.* at 670-72. The Sixth Circuit went on to hold that when plaintiffs rely on such a causation expert in obtaining a favorable liability verdict, the admission of the opinion is reversible error justifying a new trial. *Id.* at 676-78.⁵

The dissenting judge in *Tamraz* argued unsuccessfully that the trial court’s decision was discretionary, and that any gaps in the causal reasoning should go to the weight and not the

⁵ The Sixth Circuit is by no means alone in this holding. *See, e.g., Sardis v. Overhead Door Corp.*, No. 20-1411 (4th Cir. Aug. 20, 2021) (opinion attached as Exhibit 2) (holding the trial court erred by holding causation experts’ lack of testing of their theories went to weight and not admissibility, and that the error was not harmless and required remand with a directed verdict in defendants’ favor). The basic issues in *Sardis* were the same as here. The relevant causation expert started with analysis of regulations he claimed the defendant had violated. *See id.* at *25-29. The Fourth Circuit held that the district court should have made the legal determination of what the regulations required, not leave it to the jury to make that decision, and that in fact there were no such requirements in the regulations. *Id.* at *29-32. The Fourth Circuit then further held the expert’s causation opinions were independently inadmissible because the expert did not actually test his causal theories in application to the specific defendant’s products. *Id.* at *32-38. The Fourth Circuit specifically rejected the argument that it was sufficient for causation purposes to opine that the defendant violated a regulation, and then leap to the conclusion that the violation caused the harm, without the expert using an objective, reliable method to test this hypothesis. *Id.* at *37-38. Finally, the Fourth Circuit in *Sardis* also noted that the Advisory Committee on Evidence Rules has recently observed that in “a number of federal cases . . . judges did not apply the preponderance standard of admissibility to [Rule 702’s] requirements of sufficiency of basis and reliable application of principles and methods, instead holding that such issues were ones of weight for the jury,” and is currently proposing to amend Rule 702, with the advisory committee’s notes to include the statement:

[U]nfortunately many courts have held that the critical questions of the sufficiency of an expert’s basis [for his testimony], and the application of the expert’s methodology, are generally questions of weight and not admissibility. These rulings are an incorrect application of Rules 702 and 104(a) and are rejected by this amendment.

Id. at *20-21 (citing Advisory Comm. on Evidence Rules, *Agenda for Committee Meeting* at *17, 105, 107 (Apr. 30, 2021) (excerpts included as attachment)). The Fourth Circuit in *Sardis*, and the Advisory Committee itself, is warning against precisely the sort of argument that Plaintiffs have relied on in their Opposition.

admissibility of the evidence. *See id.* at 683-84. Plaintiffs make the same argument here. *See Opp.* at 17-19. Again, though, they cite no actual Sixth Circuit authority to overcome the clear, contrary holdings in *Nelson* and *Tamraz*.

Instead, Plaintiffs hope that the Court will accept their argument that because a factfinder will be resolving the disputed issue of which of the CT3 defendants (if any) actually caused the alleged harms, *see* CT1 Causation Order at *9, an expert can propound untested hypotheses and stack speculative inferences on that subject. *See Opp.* at 18 (citing CT1 Causation Order). They are incorrect. It would directly contradict the Sixth Circuit’s binding precedents to admit Rafalski’s testimony simply because it addresses an issue before the factfinder. *See Tamraz*, 620 F.3d at 667 (holding although causation testimony on the subject was generally permissible, the expert “fell short of what *Daubert* requires and his specific testimony should be excluded”).

The Court should not allow the Plaintiffs to wrap their desired ultimate conclusions in the testimony of a causation expert who opines based on speculation and bald assumptions, and call it expert opinion evidence. The Sixth Circuit has held that admitting such causation opinions is a reversible error requiring remand for new trial—an outcome which would thwart the essential purpose of the bellwether trial structure.

II. CONCLUSION

It is a matter of justice for Moving Defendants, but also of the practical administration of these bellwether cases, that Rafalski’s opinions not be admitted as to Moving Defendants in CT3. Rafalski disregarded the Court’s holding in CT1 about the permissible boundaries of his opinions. Rafalski, on instructions from Plaintiffs’ counsel, used an indiscriminate, made-for-litigation method to analyze Moving Defendants’ SOM systems, despite knowing from his own professional experience he was failing to do the many important tasks he would have done when acting as a DEA Diversion Inspector. Then, starting with the inadmissible legal conclusion that

Moving Defendants violated their statutory and regulatory duties, Rafalski leapt to Plaintiffs' desired causal conclusion that Moving Defendants' opioids flooded the illicit markets in Lake and Trumbull County, without doing anything to actually test this hypothesis.

Rafalski's opinions are inadmissible under binding Sixth Circuit precedent, and the Court should exclude Rafalski's opinions as to Moving Defendants.

Dated: August 27, 2021

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, the undersigned, hereby certify that the foregoing document was served via e-mail to all counsel of record on August 27, 2021.

/s/ Scott D. Livingston